PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

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Applicant's or agent's file reference	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
6627PC1022		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US01/43758	16 November 2001 (16.11.2001)	16 November 2000 (16.11.2000)

International Patent Classification (IPC) or national classification and IPC

IPC(7): C12P 1/20; A01N 63/00 and US Cl.: 435/41, 43, 106, 117, 252.1, 7.32, 7.23, 71.3, 440; 424/115, 116, 93.4, 155.1, 174.1

Applicant

THE REGENTS OF THE UNIVERISTY OF CALIFORNIA

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 2 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 1 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of report with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
11 June 2002 (11.06.2002)	24 August 2004 (24.08.2004)
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Irene Marx Telephone No. (571) 272-0926

Form PCT/IPEA/409 (cover sheet)(July 1998)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US01/43758

I. Basis of the report

1. With regard to the elements of the international application:*

☒ the international application as originally filed.

☒ the description:
pages 1-24 as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

☒ the claims:
pages 25 and 26, as originally filed
pages NONE, as amended (together with any statement) under Article 19
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

☒ the drawings:
pages 1-2, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

☐ the sequence listing part of the description:
pages 1, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination(under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☒ contained in the international application in printed form.

☒ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:

☒ the description, pages none

☒ the claims, Nos. none

☒ the drawings, sheets/fig none

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*
** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US01/43758

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims 7-12	YES
	Claims 1-6	NO
Inventive Step (IS)	Claims NONE	YES
	Claims 1-12	NO
Industrial Applicability (IA)	Claims 1-12	YES
	Claims NONE	NO

2. CITATIONS AND EXPLANATIONS
Please See Continuation Sheet

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

V. 2. Citations and Explanations:
Claims 1-6 lack novelty under PCT Article 33(2) as being anticipated by Helmke et al.. The claims are directed to a genus of Actinomycetales which comprises an obligate requirement for sodium and which has characteristic rRNA sequences and a method of growth a strain and recovering a biomolecule.

Helmke et al. discloses a genus of Actinomycetales which comprises an obligate requirement for sodium and which has characteristic rRNA sequences. See, e.g., Helmke et al. page 137. The reference also discloses methods of growing the strains and recovering cellular products having pharmaceutical activity, including compositions having antibiotic, antifungal and anticancer activity such as mycolic acids (See, e.g., Helmke page 129, col. 1.

Claims 1-12 lack an inventive step under PCT Article 33(3) as being obvious over Helmke et al. in view of Moran et al. and Jensen et al. and further in view of Colquhoun et al. and Crueger et al..

The claims are directed to a genus of Actinomycetales which comprises an obligate requirement for sodium and which has characteristic rRNA sequences.. The claims are also directed to method of culturing a strain of actinomycete having an obligate requirement for sodium and which has characteristic rRNA sequences and recovering the products produced. The claims further encompass a method of drug discovery by growth of a strain of actinomycete having an obligate requirement for seawater and which has characteristic rRNA sequences, and the collection and analysis of the strain or its growth media for pharmacologic activity.

Each of Helmke et al. and Moran et al. discloses a strain of Actinomycetales which comprises an obligate requirement for sodium or seawater and which has characteristic rRNA sequences. See, e.g., Helmke et al. page 137 ; Moran et al. page 1699. At least Helmke *et al.* also culture the strains of Actinomycetes having an obligate requirement for sodium or seawater. Note that the strains per se are recovered, and are subjected to extensive chemical and physiological analyses, to recover mycolic acids, for example. These compounds are recognized to have pharmacologic activity as antibiotics, and antifungal and anticancer agents. Note also that Jensen et al., for example, disclose that many Actinomycetes require seawater for growth (See, e.g., page 1107, paragraph 3) . These strains were also grown and analyzed. Note also that Colquhoun et al. discloses extensive studies of deep-sea *Actinomycetes,* which can reasonably be presumed to have obligate seawater requirements as suggested by Jensen *et al.* (See, e.g., pages 364).

The references differ from the invention as claimed in that the products produced were not analyzed for pharmacologic activity. However, Crueger et al. adequately demonstrate that the screening for metabolites having useful pharmacologic

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

activity is the essence of biotechnology (See, e.g., pages 4-8). In addition, the reference also discloses that the use gene cloning is an old and well known technique in this art to improve and accelerate the production of useful pharmaceutical compounds in order to successfully treat recalcitrant diseases such as those caused by viruses, bacteria and fungi and cancer.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process of Helmke et al., Moran et al., Jensen et al. and Colquhoun et al. of isolating, growing and analyzing Actinomycetes having requirements of sodium or seawater, by testing the strains and/or the products produced thereby for pharmacologic activity, as suggested by the teachings of and Crueger et al. for the expected benefit of maximizing the drug discovery to obtain pharmaceutically active compounds suitable to successfully treat damaging diseases while minimizing side effects.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

---------- NEW CITATIONS ----------